

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
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<b>THIS DOCUMENT RELATES TO:</b>	)	Hon. Patti Saris
	)	
<i>United States of America ex rel. Ven-a-Care of</i>	)	Magistrate Judge Marianne Bowler
<i>the Florida Keys, Inc., v. Abbott Laboratories,</i>	)	
<i>Inc.,</i>	)	
CIVIL ACTION NO. 06-11337-PBS	)	

**CONSOLIDATED MEMORANDUM BY THE UNITED STATES  
IN OPPOSITION TO ABBOTT'S EMERGENCY MOTION TO COMPEL  
THE PRODUCTION OF IRA BURNNEY DOCUMENTS  
AND**

**SUR-REPLY IN SUPPORT OF THE OPPOSITION TO ABBOTT'S MOTION  
TO COMPEL RESPONSES TO DOCUMENT REQUEST NOS. 37 AND 38**

Abbott Laboratories Inc.'s (Abbott's) Motion to Compel the Production of Ira Burney Documents (Dkt. 4892) ("Motion for Burney Documents") substantially overlaps with an earlier motion by this defendant. On October 11, 2007, Abbott moved to compel the United States to produce material from two particular sources at CMS.<sup>1</sup> (Dkt. 4790/91). Those sources are (1) records maintained as "Rulemaking Support Files" and (2) CMS's Office of Legislation. The Motion for Burney Documents concerns a subset of material from the Office of Legislation, which is the office at which Mr. Burney is, and for many years has been, employed. In the Government's view, Abbott's October 11 motion already covers the Ira Burney documents. Accordingly, this brief in opposition to the latter motion is also, effectively, a sur-reply to

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<sup>1</sup> "CMS" is the acronym for the Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration.

Abbott's Reply to the Memorandum by the United States in Opposition to Abbott's Motion to Compel Responses to Document Request Nos. 37 and 38 (Dkt. 4890).

As indicated in the United State's Memorandum in Opposition to Abbott's Motion to Compel Responses to Document Request Nos. 37 and 38 (Dkt. 4869), the Government has withheld from production documents from the Office of Legislation which reflect the agency's internal deliberations regarding policies under consideration for promulgation in federal regulations and statutes based on the deliberative process privilege and the lack of relevance of this material. The points and authorities set out in that brief are also responsive to Abbott's Motion for the Burney Documents. Accordingly, the United States adopts and incorporates herein the content of that brief which was filed on November 2, 2007.

In light of Abbott's assertions in the Motion for Burney Documents, the Government reiterates that it has not refrained from producing documents reflecting the *factual information* which CMS has known about the actual acquisition costs of drugs over the last twenty or more years. The documents from Office of Legislation withheld from production relate to the *internal deliberations* concerning the promulgation and articulation of CMS policy. Abbott's reply brief and its more recent motion to compel continue to conflate the distinction between the two types of documents. The distinction is important because it is one that Judge Saris's recent order on an Abbott motion effectively recognized. Indeed, to a very large degree, Abbott's latest briefs simply reiterate arguments that have already been rejected by the Court.

**A. The Court Has Already Considered and Rejected Abbott's Arguments Regarding Its Need for the Deliberative Material**

The central argument in Abbott's motion for the production of material from the files of Ira Burney is that such "documents may demonstrate 'not only what the Government understood

about AWP, but also *why* it consistently acquiesced in or approved of an AWP-based payment methodology after being fully informed that AWP typically exceeded actual acquisition costs by significant amounts.”<sup>2</sup> This argument has already been considered by both the Magistrate and presiding Judge in the context of motions to compel by Abbott and found wanting. When Abbott attempted to compel the production of material withheld under the deliberative process privilege last March, it argued that the Government had asserted the privilege for documents which were “highly relevant to its knowledge about drug spreads and *the reasons behind its decisions* of what, if anything, to do about those spreads.”<sup>3</sup>

In response to Abbott’s motion for the production of a broad scope of documents relating to Governmental policy-making with respect to its AWP-based payment methodology, on August 13, 2007, the Magistrate issued an order directing the Government to produce only “documents that expressly reference Abbott Laboratories, Inc. and/or the subject drugs as well as the documents that concern the government’s knowledge of the common use of spreads with respect to published AWPs...” (Dkt. 3960). In its ensuing objections to the Magistrate’s Order, Abbott stated the same arguments that it now repeats in the brief supporting the Motion to Compel Burney Documents. At that time, Abbott argued that by withholding documents relating to AWP policymaking, “the Government would prevent the jury from learning *why CMS used AWP*” and that such evidence “sheds light on why Government officials continued to rely on published drug

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<sup>2</sup> Motion for Burney Documents, at 4 (emphasis supplied) (quoting Abbott’s Reply In Support of Its Motion to Compel Discovery Responses To Its Document Requests Nos. 37 and 38, at 6).

<sup>3</sup> Abbott’s Memorandum in Support of Its Renewed Motion to Compel Evidence Withheld Under the Deliberative Process Privilege, at 7 (Dkt. 3960) (emphasis supplied).

prices despite extensive knowledge that they did not represent a reliable indication of acquisition costs.”<sup>4</sup>

Notwithstanding Abbott’s argument that the Court should dramatically broaden the scope of the material which the Government should be compelled to produce, Judge Saris narrowed the class of material that would be deemed potentially relevant and further directed that the responsive documents be produced to the Court for *in camera* review rather than produced directly to defendants. *See* Order of Nov. 9, 2007 (Dkt. 4885). Under Judge Saris’s Order, the only documents which the Government was required to submit for *in camera* inspection are those which “relate to [the Government’s] knowledge of a ‘spread’ for Abbott’s drugs *at issue in this litigation* or its knowledge of Abbott’s ‘marketing the spread’ for any of its drugs” (emphasis supplied).

CMS’s Office of Legislation is involved in high-level policy development. *See* Donald Johnson Declaration, ¶¶ 3,4.<sup>5</sup> Abbott’s objections to the Magistrate’s August Order were expressly premised on its understanding that limiting the Government’s production to documents which reference Abbott’s drugs would exclude the bulk of the internal policy-development material from the production. As one would expect, the Government does not promulgate overarching Medicare payment policies by reference to the conduct of a single provider or company. Clearly, the argument stated by Abbott here has already been raised with both the Magistrate and the presiding Judge. Both found Abbott had not presented sufficient grounds for compelling the

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<sup>4</sup> Abbott Laboratories, Inc.’s Objections to Magistrate Bowler’s August 13, 2007 Order, at 13, 20 (Dkt. 4698) (emphasis in the original).

<sup>5</sup> Exhibit 4 at Dkt. 4869.

Government to produce a broad class of privileged material. Abbott's arguments carry no greater weight in the context of a motion to compel the production of Mr. Burney's documents.

Finally, for a fuller explication of the lack of relevance of the material in question, both in light of the summary judgement decision by Judge Saris in the MDL and under First Circuit precedent, the Government respectfully refers the Court to the points and authorities set out in the Memorandum by the United States in Opposition to Abbott's Motion to Compel Responses to Documents Requests Nos. 37 and 38, at 13-16.

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**B. Abbott's Brief Does Not Accurately Describe the Documents That Are Being Withheld from Production**

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In support of its motions to compel, Abbott makes assertions which are simply not accurate. First, Abbott asserts that the United States has engaged in a “wholesale” withholding of documents and a “blanket” assertion of privilege].<sup>6</sup> Abbott states further that “communications with *outside parties* are not protected [by the deliberative process privilege].”<sup>7</sup> Clearly, Abbott would have the Court assume that the Government has refused to produce this category of material. The United States, however, has been very clear with Abbott's counsel that correspondence between CMS and outside parties, including Congress, has been, and will continue to be, produced. For example, the Declaration of Donald Johnson, Deputy Director of CMS's Office of Legislation, states: “Some of the documents in the 8 boxes [of potentially responsive documents form the Office of Legislation] are final versions of legislation, regulations, OIG and GAO reports, letters to Congress and members of the public, many of

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<sup>6</sup> Motion to Compel Burney Documents, at 4.

<sup>7</sup> *Id.* at 6 (emphasis by Abbott).

which are publicly available or being produced by other offices. Nonetheless, we will produce these documents.” Johnson Declaration, ¶ 7.<sup>8</sup> Indeed, the Government has even directed Abbott’s attorneys to the locations within the Government’s document production where CMS correspondence with Congress and outside parties has already been produced. *See, e.g.* DOJ Ltr dated Nov. 20, 2007 (Exhibit 1 to this memorandum).

Separate and apart from issues and arguments in Abbott’s briefs, with respect to the material from the Office of Legislation described in the Johnson Declaration, the Government has a correction to state. In responding to Abbott’s motions and in undertaking the efforts to produce the non-privileged material described in paragraph seven of Mr. Johnson’s Declaration, the Government has acquired more detailed information about the number of documents that comprise the Office of Legislation material as to which Abbott has moved to compel production. It now appears that the original estimate in the Johnson Declaration, which was based on a partial review of the boxes, was too high and the Court should not rely on that number when considering the burden associated with creating a document-specific privilege log for this source of material. The Government still estimates, however, that the boxes from the Office of Legislation contain in excess of 2600 documents. The relevancy and burdensomeness objections and other points stated in response to Abbott’s motion to compel provide more than sufficient grounds upon which to deny Abbott’s motions.

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<sup>8</sup> Exhibit 4 at Dkt. 4869.

**CONCLUSION**

For the foregoing reasons, Abbott's motion to compel the production of Ira Burney documents, as well as the motion to compel the production of documents responsive to Requests for Production Nos. 37 and 38, should be denied.

Respectfully submitted,

For the United States of America,

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Dated: December 11, 2007

**CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above MEMORANDUM BY THE UNITED STATES IN OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION TO COMPEL THE PRODUCTION OF IRA BURNEY DOCUMENTS AND SUR-REPLY IN SUPPORT OF THE OPPOSITION TO ABBOTT'S MOTION TO COMPEL RESPONSES TO DOCUMENT REQUEST NOS. 37 AND 38 to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: December 11, 2007

/s/  
Justin Draycott